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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,487	08/23/2001	Robert F. Rioux	BSC-187 (1002/257)	1401
21874	7590	09/07/2005	EXAMINER	
EDWARDS & ANGELL, LLP			PELLEGRINO, BRIAN E	
P.O. BOX 55874				
BOSTON, MA 02205			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/935,487		RIOUX ET AL.	
	Examiner		Art Unit	
	Brian E Pellegrino		3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed (~~6/13/05~~) in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's AF submission filed on 4/15/05 has been entered.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3,7 are rejected under 35 U.S.C. 102(b) as being anticipated by Bosley (5514176. Bosley illustrates (Fig. 2) a coil segment **14** with a middle portion **24** and proximal and distal windings spaced from each other. Bosley discloses that the middle portion has a diameter less than the proximal and distal ends, col. 5, lines 53-56. Bosley also shows a flexible polymer material **20** that encapsulates a portion of the coil segment. Fig. 1 shows the polymer forms a webbing between the windings. Bosley additionally discloses the flexible polymer material is silicone col. 4, lines 26-29. Bosley also discloses the coil can be a biocompatible wire made from steel or titanium, col. 4, lines 65-67. The examiner asserts that the claimed physical properties (low durometer)

Art Unit: 3738

are present in the prior art silicone material to some extent even though they are not explicitly recited. Therefore, the examiner hereby burdens the applicant to show that these properties are not present in the prior art.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4,6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bosley '176 in view of Yachia et al. (5246445). Bosley is explained supra. However, Bosley does not disclose a cross-sectional area of the wire within the range of 0.0079mm^2 to 7.1mm^2 or the use of hooks at each of the proximal and distal ends of the prosthetic device. Yachia et al. teach a cross-sectional area of 0.0079mm^2 to 0.785mm^2 col. 4, lines 44,45. Yachia et al. also teach (Fig. 1a) a stent with hooks 3 at both the proximal and distal ends of the coil body for connection to a delivery system, col. 6, lines 13-16. It would have been obvious to one of ordinary skill in the art to use a wire with the cross-sectional area as taught by Yachia et al. with the device of Bosley in order to provide some greater structural support with the larger cross-sectional area wire. It would also have been obvious to one of ordinary skill in the art to incorporate hooks at both proximal and distal ends of a stent as taught Yachia et al. in the device of Bosley such that the vessel apparatus does not dislodge from the instrument used to implant it. The addition of the hooks enables the surgeon to precisely place the vessel-opening device in its location without the apparatus being displaced during insertion.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bosley '176 in view of Hachtman et al. (5645559). Bosley is explained supra. However, Bosley does not disclose a low durometer silicone within the range of 0-60D. Hachtman et al. also teach that a silicone layer is placed on the stent to provide a barrier that prevents the growth of tissue through the stent and to support the flow of fluid through the lumen, col. 2, lines 14-18. Hachtman et al. also teach that low durometer silicone, such as 30D is placed on a stent, col. 4, lines 49-52. It would have been obvious to one of ordinary skill in the art to use a 30D silicone as taught by Hachtman et al. for the silicone on Bosley's stent such that fluid flow is maintained through the lumen of the device while preventing tissue ingrowth.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zukowski et al. in view of Bosley (5514176). Zukowski et al. show (Figs. 16,17) a stent device having a coil segment with windings spaced apart from each other and a flexible polymer encapsulating the coil segment. Zukowski discloses the wound element is a steel wire (page 8, line 35, page 9, lines 25-30) that is encapsulated by the polymer. However, Zukowski et al. fail to disclose the distal and proximal portions having a diameter greater than the middle portion of the coil segment. Bosley teaches that the proximal and distal ends of the stent are greater than the middle portion to prevent migration of the device, col. 4, lines 58-61. It would have been obvious to modify the ends of the device to be flared as taught by Bosley with the apparatus of Zukowski et al. such that it accommodates the structure of the vessel it is used with, such as going from a larger lumen to a smaller and then larger.

Response to Arguments

Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 7:30am to 5pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian E Pellegrino